

*Applicant: Phillips et al.*  
*Application Serial No. 09/735,363*  
*Amendment and Response to Office Action*  
*Page 4 of 7*

### REMARKS

By this amendment, Applicants cancel Claim 6. Claims 1-5, 7-8, 10-20, 22-28, and 42-25 are now pending in the above-identified patent application. Of the above, Claims 11-20, 22-28, and 42-45 are withdrawn from consideration. By this amendment, Claims 2-5 are amended to correct unintentional typographical errors. No new matter is introduced by the amendments. Reexamination and reconsideration of the application are requested in view of these amendments and the following remarks.

#### *Supplemental Information Disclosure Statement*

Applicants respectfully bring to the Examiner's attention that the Supplemental Information Disclosure Statement and Appendix A were timely submitted on March 11, 2002. Applicants respectfully request Examiner to consider documents cited in the Supplemental Information Disclosure Statement and Appendix A.

#### *Claim Rejections under 35 U.S.C. §112, second paragraph*

The Examiner rejects Claim 10 under 35 U.S.C. §112, second paragraph, as indefinite and asserts that Claims 6 and 10 appear to be duplicate claims. By this amendment, Applicants cancel Claim 6. Applicants respectfully assert that cancellation of Claim 6 overcomes the rejection and request its withdrawal.

#### *Claim Rejections under 35 U.S.C. §112, first paragraph*

The Examiner rejects Claims 1-6 and 10 under 35 U.S.C. §112, first paragraph, for reasons of inadequate written description. The Examiner asserts that

“[t]he specification and claims do not indicate what distinguishing attributes are concisely shared by the members of the genus comprising the nucleotide compositions between 2 and 20 bases that are

*Applicant: Phillips et al.*  
*Application Serial No. 09/735,363*  
*Amendment and Response to Office Action*  
*Page 5 of 7*

depicted in the various formulae in claim 1 and which are useful for inducing a response in an animal having cancer."

Applicants respectfully submit that Claim 1 indicates the distinguishing attributes shared by the members of the claimed genus. The members of the genus claimed in Claim 1 are 2 to 20 base, 3'-OH, 5'-OH synthetic phosphodiester oligonucleotides. The members of the claimed genus also share the distinguishing feature of comprising GT-containing nucleotide sequences defined by  $(G_xT_y)_n$ , wherein x and y is an integer between 1 and 7, and n is an integer between 1 and 12. Another distinguishing feature is the ability to induce a response in an animal having cancer. These distinguishing features are described in the Specification on page 9, lines 17-24. Further, in Examples 4-37, the Specification provides a number of species of the claimed genus and describes the characteristics identifying the members of the genus. For example, the Specification states, on page 16, lines 5-6, that "Jurkat T cell proliferation was inhibited by the GT sequences tested, but not by the CT sequence tested", on page 26, lines 2-4, that "6 base GT-phosphodiester sequences inhibited Jurkat T, LNCaP and MCF-7 cell proliferation more effectively than 6 base GT-phosphorothioate sequences", and, on page 27, lines 4-7, that "substitution of a sulfur atom for a nonbridging oxygen atom on one or more phosphate groups of 6 base GT SEQ ID NO:25 resulted in a significant decrease in inhibition of Jurkat T and MCF-7 cell proliferation."

Applicants respectfully assert that the disclosure provides sufficient description of the defining features of the claimed genus, and a representative number of species. In view of the foregoing, applicants respectfully request withdrawal of the rejection.

*Applicant: Phillips et al.*  
*Application Serial No. 09/735,363*  
*Amendment and Response to Office Action*  
*Page 6 of 7*

*Claim Rejections under 35 U.S.C. §102*

The Examiner rejects Claims 1-3, 5, 7, and 8 under 35 U.S.C. §102(b) as anticipated by *Frank et al.* (International Patent Application PCT/EP96/02427). The Examiner asserts that

“Frank et al teach compositions comprising an oligonucleotide SEQ ID NO: 45 (between 2 and 10 nucleobases), and further comprising a chemotherapeutic agent and a pharmaceutically acceptable carrier (See especially pages 17, 42-43, Accession No. AAT80306, and the accompanying sequence alignment data).”

Applicants respectfully assert that *Frank et al.* does not teach a composition comprising oligonucleotide SEQ ID NO:45. Applicants respectfully bring to the Examiner's attention that oligonucleotide (or “sequence”, as defined by the Specification on page 5, line 23) SEQ ID NO:45 is a 3'-OH, 5'-OH synthetic phosphodiester hexaoligonucleotide GGGAGG. *Frank et al.* does not teach a 3'-OH, 5'-OH hexaoligonucleotide GGGAGG (see *Sequence Listing* in *Frank et al.*, pages 58-82). None of the oligonucleotides taught on page 17 of *Frank et al.* is the 3'-OH, 5'-OH synthetic phosphodiester hexaoligonucleotide GGGAGG. Oligonucleotide Accession No. AAT80306 is a nine-base oligonucleotide HCV-186 CCCGGGAGG taught in *Frank et al.*, not 3'-OH, 5'-OH synthetic phosphodiester hexaoligonucleotide GGGAGG (SEQ ID NO:45).

In view of the foregoing, applicants respectfully assert that Claims 1-3, 5, 7, and 8 are not anticipated by *Frank et al.* Applicants request withdrawal of the rejection.

*Applicant: Phillips et al.*  
*Application Serial No. 09/735,363*  
*Amendment and Response to Office Action*  
*Page 7 of 7*

### CONCLUSION

The foregoing is submitted as a full and complete response to the non-final Office Action mailed December 17, 2002. Applicants assert that the claims are now in condition for allowance and respectfully request that the application be passed to issuance. If the Examiner believes that any informalities remain in the case, which may be corrected by Examiner's amendment, or that there are any other issues which can be resolved by a telephone interview, a telephone call to the undersigned agent at (404) 815-6500 is respectfully solicited.

No additional fees are believed due, however, the Commissioner is hereby authorized to charge any deficiencies which may be required or credit any overpayment to Deposit Account Number 11-0855.

Respectfully submitted,

KILPATRICK STOCKTON LLP

*Elena S. Polonikova*

By: Elena S. Polovnikova, Ph.D.  
Patent Agent  
Reg. No.: 52,130

KILPATRICK STOCKTON LLP  
1100 Peachtree Street, Suite 2800  
Atlanta, GA 30309-4530  
Phone: (404) 815-6500  
Facsimile: (404) 815-6555  
Atty. Docket: 02811-0181 (42368-250224)